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| 10/773,786 | 02/06/2004 | Kenneth A. Alley | ALLE-P11-US | 7917 |

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| EXAMINER |
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HAND, MELANIE JO

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| ART UNIT | PAPER NUMBER |
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3761

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09/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/773,786

Applicant(s)

ALLEY, KENNETH A.

Examiner

Melanie J. Hand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-19 have been considered but are moot in view of the new ground(s) of rejection.

With respect to applicant's argument regarding amended claims 1 and 18: Applicant argues that Severin does not teach the two-piece construction of the claimed device. This is not found persuasive. The third piece, a container connector, is attached to the applicator head substantially all of the time during which the applicator is used and forms two pieces, the applicator/connector as one piece and the container as a second piece, whenever the activation mechanism is in use and the two piece configuration is necessarily present for the piercing means to be activated and the device to be used. The device of Severin teaches all of the claim rejections and thus teaches the claimed two-piece construction. Thus, the argument is insufficient to overcome the rejection. Applicant further argues that Severin does not teach a piercing means that is integrated into the applicator head because the piercing means is located on the connector 24. This is not found persuasive. Applicant is referred to Col. 7, lines 6,7, wherein Severin teaches "a seal piercing member 30 on the gel formulation dispenser 16 (i.e. the applicator head)". Severin is clearly teaching that the piercing means is integrated into the applicator head.

Applicants' arguments with regard to the rejection of claims under 35 U.S.C. 103 have been fully considered but are not persuasive as Applicants' arguments depend entirely on Applicants' arguments regarding the rejection of claims 1 and 18, which have been addressed *supra*. Further, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are

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based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Severin teaches the claimed two-piece construction and the integrated piercing means, thus it is not required that Macartney teach these limitations. Examiner has restated the rejection headings to reflect which grounds of rejection apply to claims 15, 17 and 19.

Claim Objections

Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 19 recites that the claimed substance is a liquid, however claim 18 already positively recites a liquid substance.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6, 10-14, 16, 18 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Severin et al (U.S. Patent No. 6,488,665).

With respect to **claim 1**: Severin teaches a device 10 for applying a substance, for example to the skin of a person, the device comprising: a container 14 having an open end with opening 20 and a closed end, said container 14 designed to store the substance (Col. 6, lines 21-39, Col. 7, lines 8-11); a pierceable barrier 22 positioned proximate said open end of the container 14 for preventing the substance from escaping said container (Col. 6, lines 59-64); an applicator head

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16 having a delivery means in the form of applicator pad 28, a passageway for the substance. Threads 38 on container connector end 34 of container connector 24 allow removable attachment of the applicator head 28 with gel dispenser 16 (passageway for delivering liquid from container to delivery means 28) to the open end of container 14. Piercing means 30 is located on the gel dispenser 16 and is thus integrated. Applicator head 16 communicates with said container 14 for attaching the applicator head 16 to the open end of said container 14 and positioning the piercing means 30 proximate said barrier 22. Delivery means 28 both assists in controlling the flow of the substance and in applying the substance. Piercing means 30 pierces said barrier 22 after said applicator head 16 is attached to the container 14 by necessarily manipulating said applicator head 16 with respect to the container 14 while attaching said head 16. The said substance is released from the container 14 and the substance is allowed to flow through the passageway to the delivery means 28. (Figs. 2,3, Col. 6, lines 21-39)

With respect to **Claim 2**: Delivery means 28 is an absorbent sponge-like pad.

With respect to **Claim 3**: A foam pad is considered herein to be sponge-like, as both a foam and a sponge are formed by identical processes.

With respect to **Claim 4**: A sponge-like pad is a hydrophilic absorbent material.

With respect to **Claim 5**: Severin teaches that delivery means 28 has a soft texture for comfort and is suited for topical medical use, of which terry cloth is an example.

With respect to **Claim 6**: Barrier 22 is comprised of aluminum foil.

With respect to **Claim 10**: Container 14 is necessarily a single dose container due to the non-resealable nature of barrier 22.

With respect to **Claims 11-13**: Gel formulation 12 is a topical medicament for application to a user's skin. The formulation comprises alcohol and iodine, and is taught by Severin to also be a topical antiseptic for sterilizing a section of the skin.

With respect to **Claim 14**: Container 14 is prefilled with a desired amount of said formulation for a surgical procedure, i.e. a pre-measured substance.

With respect to **Claim 16**: Gel formulation 12 is comprised of gel, which is a viscous substance.

With respect to **claim 18**: Severin teaches an applicator device 10 for dispensing a liquid substance, the device comprising: a container 14 for storing the liquid substance, the container 14 having an open end with opening 20 and a closed end and a locking ridge that mates with lock 32 that extends from the container 14 at its neck 18 proximate the open end 20. (Col. 7, lines 44-47) A pierceable barrier 22 is located over said open end 20 of the container for sealing in the liquid substance (Col. 7, lines 8-11) Applicator head 16 has an absorbent pad 28 at a first end, locking grips 46,48 proximate a second end, which is defined by the end of elongate tube 36 connected to the end of connection end 34 that connects applicator head 16 to container 14. Device 10 has an integrated piercing means 30, and a tubular section in the form of connector 24 for providing a passage between the pad 28 and the open end of the container 14 (Figs. 2,3). The tubular section 24 meets the claim limitation and thus inherently and necessarily doubles as

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a handle for allowing a user to grasp and manipulate the applicator head 16. The locking ridge and said locking grips 46,48 of lock 32 communicate with each other when the applicator head 16 is placed on the container 14 for securing the applicator head 16 to the container and thus positioning said piercing means 30 integral to head 16 in close proximity to the barrier 22 of container 14 (Figs. 2,3, Col. 7, lines 44-65). An activation mechanism is taught by Severin in the form of engaging said locking ridge and locking grips 31 for moving said piercing means 30 into contact with said barrier 22 in order to pierce said barrier 22 thereby releasing the liquid solution into the tubular section 24 and allowing the liquid solution to be absorbed by the pad 28. (Col. 6, lines 23-39, Col. 7, lines 4-20)

With respect to **claim 20**: The activation mechanism comprises a tapered flange positioned on the container 14 between said locking ridge and said open end 20 of the container (Fig. 2), and a threaded ridge 38 formed in the tubular section of said applicator head 16 positioned between said locking grips 31 and said pad 28, said threaded ridge 38 communicating with said tapered flange 40 such that when said applicator head 16 is turned with respect to said container the piercing means 30 pierces said barrier. (Fig. 2, Col. 7, lines 4-20,44-47)

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 7, 15, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Severin et al (U.S. Patent No. 6,488,665).

With respect to **Claim 7**: Seal piercing means 30 (means associated with applicator head for piercing barrier 22) is a projection. Since the means is intended to pierce barrier 22, it necessarily has a sharp component. However, Severin teaches that this component is a sharp point, not a sharp edge. However, it would be obvious to one of ordinary skill in the art to modify the piercing means 30 so as to comprise a sharp edge with a reasonable expectation of success, as a sharp edge would provide the function of a piercing means equally as well as a point, and there are only a finite number of solutions to meet this design need. Specifically, a piercing means can necessarily only be either a one-dimensional point, or a two or three-dimensional edge. If there is a design need or a market pressure to solve a problem, and there are a finite number of identified, predictable solutions, a person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007)

With respect to **Claim 15**: Severin does not explicitly teach that delivery system 10 is sold and/or delivered in a tamper-proof packaging, however it would be obvious to one of ordinary skill in the art to provide such a packaging for system 10, as the individual systems have a one-time use in surgical procedures, thus they are prone to tampering and are used in sterile environments and the systems 10 are therefore required to be sterile themselves.

With respect to **Claims 17,19**: Severin does not teach a powdered substance or a liquid, however container 14 is capable of holding such substances, and the delivery means is capable of transporting a powder to the applicator head where such powder would be administered to a

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user's skin, therefore it would be obvious to one of ordinary skill in the art to use the delivery system taught by Severin to deliver a powdered formulation or a liquid formulation as opposed to a gel formulation.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Severin et al (U.S. Patent No. 6,488,665) in view of Macartney et al (U.S. Patent No. 5,306,270).

With respect to **Claims 8,9**: Severin does not explicitly teach that said barrier 22 is a plug comprised of plastic material penetratable by said piercing means 30. Macartney teaches a sealing closure plug cap 18 comprised of thermoplastic elastomeric material (i.e. plastic) and having an opening for accepting a needle. Macartney teaches that the plug provides an airtight seal about the opening of a vial or tube, therefore it would be obvious to one of ordinary skill in the art to substitute a plug as taught by Macartney for the foil liner barrier taught by Severin with a reasonable expectation of success, as such a plug is also capable of creating a gas-impermeable seal that prevents the gel taught by Severin from escaping its container.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

September 17, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

